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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,849	12/14/2001	Jason P. McDevitt	03768/09630	7436

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EXAMINER

LEWIS, KIM M

ART UNIT PAPER NUMBER

3743

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/016,849

Applicant(s)

MCDEVITT ET AL.

Examiner

Kim M. Lewis

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 10-29 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 10-29 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Detailed Action</u> . |

DETAILED ACTION

Response to Reply

1. The reply including a 1.131 affidavit filed on 1/24/05 has been received and made of record. The affidavit has been reviewed and the Edwards et al. is no longer available as prior art. The arguments presented in the reply will be addressed in the Response to Arguments section below.
2. Claims 1-5, 10-29 and 32 are pending.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

Art Unit: 3743

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 2, 4, 5, 10-16, 18-21, 23-35, 27-29 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,156,334 ("Meyer-Ingold et al.") in view of WO 97/07273 ("Ninagawa").

As regards claims 1, 2, 19, 24 and 25 and Meyer-Ingold et al. substantially disclose the instant invention. Meyer-Ingold et al. disclose wound coverings for removal of interfering factors from wound fluid. The invention is achieved by covalently bonding substances (enzymes, proteins, etc. (col. 2, lines 51-60)) that interact (*i.e.*, remove or eliminate) with interfering factors (proteases) present in wound exudates to a carrier material. Meyer-Ingold et al. further disclose the use of growth factors in combination with the interfering factors in order to improve the healing process of chronic wounds (col. 3, lines 26-34). Specifically, Meyer-Ingold et al. disclose that wound dressings (*e.g.*, dressing gauze, bandages, compresses, cotton-wool, patches, foil, *etc.*) known in the prior art can be modified by covalently bonding the trapper molecules thereto and simultaneously applying wound healing promoting substances such as protein containing growth factors (col. 5, line 1-col. 10, line 4) in the wound.

As to the method, although the steps are not explicitly stated, the process of making the disclosed wound dressing and then applying the wound dressing to a user

reads on the steps of the instant invention. Moreover, the “trapper molecules” are **capable** of withdrawing, entrapping and removing a protease from the wound site.

Meyer-Ingold et al. fail to teach that the carrier material (wound dressing) consists essentially of protein fibers. However, Ninagawa discloses the use of surgical gauze prepared from short silk fibers.

It would have been obvious to one having ordinary skill in the art to select the surgical gauze of Ninagawa, which consists of silk (protein) fibers, as the carrier material since Meyer-Ingold et al. disclose that wound coverings known in the prior art can be modified and used in the invention.

Additionally, the specific step of “selecting” is inherently accomplished when the silk surgical gauze is used.

As regards claims 4, 5, 27 and 28, the fibers are in the form of a silk fabric (gauze).

As regards claim 10-14, Meyer-Ingold et al. fail to explicitly teach that the class proteases (col. 5, lines 4-11) comprises elastase, neutrophil elastase, gelatinase, or gelatinase B (NNP-9). However, it clear from the disclosure that more than one type of protease is intended for interference due to the plural use of the term proteases.

In view of the plural disclosure of Meyer-Ingold et al. it would have been *prima facie* obvious to one having ordinary skill in the art to select a wound dressing (fibers) having trapper molecules covalently bonded thereto, which would remove any type of protease including elastase, neutrophil elastase, gelatinase, or gelatinase B (NNP-9), that would interfere with the wound healing process.

Art Unit: 3743

As regards claims 15 and 20, Meyer-Ingold et al. disclose at col. 9, line 65-col. 10, line 4 that the wound healing substances, such as for example, growth factors can be applied into the wound, thereby being separate from the wound dressing.

As regards claims 16 and 21, Meyer-Ingold et al. fail to disclose that the growth factor is in form of an ointment, lotion, solution or gel. Absent a critical teaching and/or a showing of unexpected results derived from the use of a growth factor in the form of an ointment, lotion, solution or gel, the examiner contends that the form of the growth factor is an obvious design choice, which does not patentably distinguish applicant's invention.

As regards claims 18, 23 and 32, note col. 10, lines 1-2, which discloses the use of PDGF (platelet derived growth factor).

As regards claim 29, Meyer-Ingold discloses that the wound dressing further comprises a non-protein-containing component in addition to the protein-containing component (col. 8, line 1-col. 10, line 6).

Claims 1, 3, 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer-Ingold et al. in view of U.S. Patent No. 5,447,505 ("Valentine").

As regards claims 1, 3, 24 and 26, Meyer-Ingold et al. substantially disclose the instant invention. Meyer-Ingold et al. disclose wound coverings for removal of interfering factors from wound fluid. The invention is achieved by covalently bonding substances (enzymes, proteins, etc. (col. 2, lines 51-60)) that interact (*i.e.*, remove or

Art Unit: 3743

eliminate) with interfering factors (proteases) present in wound exudates to a carrier material. Meyer-Ingold et al. further disclose the use of growth factors in combination with the interfering factors in order to improve the healing process of chronic wounds (col. 3, lines 26-34). Specifically, Meyer-Ingold et al. disclose that wound dressings (e.g., dressing gauze, bandages, compresses, cotton-wool, patches, foil, etc.) known in the prior art can be modified by covalently bonding the trapper molecules thereto and simultaneously applying wound healing promoting substances such as growth factors (col. 9, line 57-col. 10, line 4) in the wound. Moreover, the "trapper molecules" are **capable** of withdrawing, entrapping and removing a protease from the wound site.

As to the method, although the steps are not explicitly stated, the process of making the disclosed wound dressing and then applying the wound dressing to a user reads on the steps of the instant invention.

Meyer-Ingold et al. fail to teach that the carrier material (wound dressing) consists essentially of protein fibers. However, Valentine discloses the use of wool, gauze, unmedicated cotton, etc. (col. 1, lines 9-15) as being a material used to treat wounds, thereby being a dressing.

It would have been obvious to one having ordinary skill in the art to select the wound treatment material of Valentine, which consists of wool (protein) fibers, as the carrier material for since Meyer-Ingold et al. disclose that wound coverings known in the prior art can be modified and used in the invention.

Additionally, the specific step of "selecting" is inherently accomplished when the cotton-wool or the wool gauze is used.

Art Unit: 3743

7. Claims 17 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer Ingold et al. in view of Ninagawa as applied to claims 1 and 19 above, and in further view of U.S. Patent No. 5,874,308 ("Kilburn et al.").

As regards claim 17 and 22, Meyer-Ingold et al. disclose the use of growth factors, however, discloses the growth factors as being applied to the user separate from the wound dressing. Kilburn et al., however, discloses compositions and methods for modulating cell proliferation using growth factors-polysaccharide binding fusion proteins. Specifically, disclosed is the binding a growth factor to a wound covering for application to a wound (col. 8, lines 31-40).

In view of Kilburn et al., it would have been obvious to one having ordinary skill in the art to provide the modified device of Meyer-Ingold with a growth factor directly bonded to the wound covering as an obvious alternative to applying the growth factor directly to the wound. This will prevent the separate step of applying a growth factor directly to the wound and shorten the time required for preparing the wound and dressing for use.

Response to Arguments

Applicant's arguments filed 1/24/05 have been fully considered but they are not persuasive. The applicants' argue that the examiner's rationale for combining Meyer-Ingold et al. with Ninagawa is based on the "obvious to try" standard, which is improper under 35 U.S.C. §103(a). In response, the examiner disagrees. The rationale to combine Meyer-Ingold et al. and Ninagawa is not based on the obvious to try" standard, rather it

Art Unit: 3743

is based on motivation provided within Meyer-Ingold et al., which states that wound dressings (e.g., dressing gauze, bandages, compresses, cotton-wool, patches, foil, etc.) known in the prior art can be modified (col. 5, line 1-col. 10, line 4). In light of this disclosure, one having ordinary skill in the art would have been motivated to select the known silk prior art dressing of Ninagawa for modification and use, as well as any other known dressing.

The applicant also argues the preferred carrier materials of Meyer-Ingold et al., which are said to include cellulose, alginate, and other polysaccharides, and synthetic polymers, and that many embodiments do not employ fibers, rather gels and films. The examiner wishes the applicants to note that while cellulose, alginate, and other polysaccharides, and synthetic polymers may be the **preferred** materials, and while the examples utilize gels and films, the other known prior art wound dressings are not precluded from modification based upon the specific disclosure at col. 5, line 1-col. 10, line 4.

In response to applicants' argument that neither of the cited references (Meyer-Ingold et al. and Ninagawa) recognized the benefits obtained by the claimed invention, the examiner disagrees. Meyer-Ingold et al. is concerned with a similar task of removing interfering factors (*i.e.*, factors that impede the with wound healing process) present in wound exudate. There are many known factors present in wound exudate that prevent wound healing, one of which is protease. Meyer-Ingold et al. further discloses that it is important that the material used to remove the interfering factor have high specificity for the interfering factor so as not to remove substances important to the

Art Unit: 3743

wound healing process (col. 2, lines 51-60). At col. 5, lines 4-11, Meyer-Ingold et al. disclose that while cellular interfering factors such as bacterial or an excess of endogenous inflammatory cells can slow down wound healing, so too can imbalanced regulatory proteins and peptides, such as proteases, etc. It is thus made clear from the disclosure that Meyer-Ingold et al. is concerned with the removal of proteases from wound exudate.

While Meyer-Ingold et al. employs the use of trapper molecules covalently bonded to the carrier material, to target specific interfering factors, the substitution of the silk gauze of Ninagawa, would only further enhance the removal of the interfering factors from the wound exudate.

In response to applicants' remarks regarding the combination of Meyer-Ingold et al. and Valentine, the examiner has clearly articulated in the rejection as well as the response to the arguments above motivation to combine Meyer-Ingold et al. and Ninagawa, thus not defects are found in combination of references. Additionally, the examiner presents the same rationale for combining Meyer-Ingold et al. and Valentine therefore claims 1 and 24 do not define over the prior art of record.

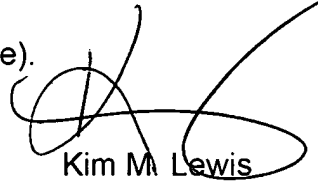
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is (571) 272-4796. The examiner can normally be reached on Mondays to Thursdays from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett, can be reached on (571) 272-4791. The fax phone

Art Unit: 3743

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197. (toll-free).



Kim M. Lewis
Primary Examiner
Art Unit 3743

kml
April 5, 2005